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ORIGINAL ARTICLE

Accuracy of the ClearSight™ system in patients undergoing abdominal aortic aneurysm surgery

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Abstract

Purpose The ClearSight™ device monitors continuous pressure and cardiac output via pulse contour analysis. ClearSight™, however, may not be reliable in patients with reduced peripheral perfusion caused by high peripheral resistance. This study aimed to elucidate the accuracy and trending ability of ClearSight™ in patients undergoing abdominal aortic aneurysm (AAA) surgery by comparing the ClearSight™-derived cardiac index (CI_{CS}) with that measured using three-dimensional echocardiography (CI_{3D}).

Methods The study included 20 patients who underwent elective AAA surgery. CI_{CS} and CI_{3D} were measured simultaneously at eight time points during the surgery. Trending ability was investigated after aortic clamping and unclamping. We used CI_{3D} as the reference method.

Results Bland–Altman analysis showed a wide limit of agreement between CI_{CS} and CI_{3D} (percentage error 41.3%). Subgroup analysis showed a lower percentage error (33.2%) in patients with CI ≥ 2.5 L/min/m^2. The cubic splines related to the CI_{3D} and CI discrepancy were negatively sloped, indicating that CI_{3D} had significant influence on the CI discrepancy ($p < 0.001$). Four-quadrant plot analysis showed that the tracking ability of ClearSight™ after aortic clamping and declamping were clinically unacceptable (81.3% and 78.6%, respectively). Also, the polar plot analysis showed that the concordance rate of ClearSight™ after aortic clamping and declamping were clinically unacceptable (58.3% and 66.7%, respectively).

Conclusions ClearSight™ was not sufficiently accurate in patients undergoing AAA surgery. The tracking ability of ClearSight™ after aortic clamping was below the acceptable limit.

Keywords Blood pressure monitor · Cardiac output · Echocardiography · Ultrasound · ClearSight

Introduction

Continuous hemodynamic monitoring is extremely important during surgery. New technology has increased the availability of cardiac index (CI) monitoring, allowing us to obtain the CI with less-invasive methods. Echocardiography is a minimally invasive monitoring method that is frequently used to measure CI. Improved technology in three-dimensional echocardiography (3DE) allows us to measure cardiac volume more precisely [1–3]. Because the measurement of cardiac volumes with 3DE has a mean percentage error (proportion between the magnitude of measurement and the error in measurement) of ≤ 20% [4–6], 3DE can be used as a reference method for measuring cardiac output or CI [7–9].

ClearSight™ (Edwards Lifesciences, Irvine, CA, USA) is a noninvasive monitor that measures arterial blood pressure and CI continuously with a finger cuff method. The device

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has been most widely studied in critically ill patients because of concerns about complications related to pulmonary arterial catheterization in that population [10]. ClearSight™ has potential advantages, including its noninvasiveness and ease of use. However, the reliability of continuous noninvasive finger-cuff blood-pressure-derived pulse contour analysis in critically ill patients who have reduced perfusion of the hand resulting from high systemic vascular resistance (SVR) has been questioned [11, 12]. The accuracy and trending ability of ClearSight™ in patients undergoing abdominal aortic aneurysm (AAA) surgery might be affected by dramatic changes in SVR secondary to aortic clamping and unclamping. However, the accuracy and trending ability of ClearSight™ in patients undergoing AAA repair remain unclear. Pulmonary arterial catheters may be too invasive in AAA surgery because of possible complications. We were very interested to determine whether the noninvasive monitor, ClearSight™, can be used in AAA surgery, during which, SVR changes dramatically. Also, whether this monitor is reliable in low CI is of anesthesiologists' interest. Therefore, we investigate the effect of low CI to the accuracy of ClearSight™.

The goal of this study was to determine the accuracy and trending ability of ClearSight™ in patients undergoing AAA surgery by comparing ClearSight™-derived CI versus 3DE-measured CI (CI_{3D}).

Methods

Patients

This single-center prospective cohort study included 20 patients who underwent elective AAA surgery from August 2017 to July 2018. The study protocol was approved by the Ethics Review Committee of the National Cerebral and Cardiovascular Center (file number: M26-040-5) and met the guidelines of the Helsinki Declaration. This study is part of the project to elucidate the accuracy of noninvasive monitor. The similar study which target at FloTrac/Vigileo™ (Edwards Lifesciences, Irvine, CA, USA) was already published [13]. The protocol and analysis methods in this study are similar to the previous study [13]. Written informed consent was obtained from all patients who participated in the study. Unless contraindicated (e.g., patient is on an anticoagulant), epidural anesthesia was used to avoid postoperative pain. Patients with contraindications to use of an epidural catheter underwent a transversus abdominis plane block postoperatively. Exclusion criteria were (1) more than mild mitral regurgitation (MR); (2) more than mild aortic regurgitation (AR); (3) arrhythmias or (4) subclavian stenosis. Valvular diseases are evaluated by intraoperative transesophageal echocardiography.

Anesthesia was induced with fentanyl (1.5–2.0 μg/kg) and propofol (1 mg/kg). Neuromuscular blockade was achieved with rocuronium 1 mg/kg. Anesthesia was maintained with sevoflurane (1.2–1.5%) and remifentanil (0.2–0.3 μg/kg/min), using mechanical ventilation to maintain end-tidal carbon dioxide at 35–40 mmHg.

After endotracheal intubation, the ClearSight™ device with a wrist unit connected to a finger cuff was attached to the patient's hand with no radial artery catheter. Also, a transesophageal echocardiography probe (X7-2t transducer; Philips Medical Systems, GmbH, Andover, MA, USA) was inserted.

Study protocol

All transesophageal echocardiography measurements were performed with a Philips iE-33 system (Philips Medical Systems, GmbH) by the same anesthesiologist, who was certified by Japanese Board of Cardiovascular Anesthesiology.

In accordance with a similar study of the FloTrac/Vigileo™ [13, 14], 3D full-volume images was obtained at eight time points: (T1) after anesthesia induction; (T2) immediately before aortic cross-clamping; (T3) immediately after aortic cross-clamping; (T4) 5 min after aortic cross-clamping; (T5) immediately before the first unclamping of the iliac artery; (T6) immediately after the first unclamping of the iliac artery; (T7) 5 min after the first unclamping of the iliac artery; and (T8) at the end of surgery. Patients' breathing was suspended while we obtain the images. Four cardiac cycles of images were acquired for offline full-volume reconstruction. CI data from ClearSight™ (CI_{CS}) and standard hemodynamic data—heart rate, MAP, MAP measured with ClearSight™ (MAPcs), central venous pressure (CVP)—were obtained simultaneously. QLAB 6.2 semiautomatic 3D volume-tracing software (Philips Medical Systems) was used to calculate CI_{3D}. We calculated the SVR index ($SVRI_{3D}$) using CI_{3D} according to the following formula:

$$SVRI_{3D} = (MAP - CVP) \times 80/CI_{3D}.$$

Calculation of CI using 3DE

We previously described a method used to determine CI with 3D volume images [7, 9, 15]. Briefly, offline left ventricular volume analysis was performed using QLAB software version 6.2, which allows us to delineate end-systolic and end-diastolic endocardial borders semi-automatically. The image is obtained with a single click; therefore, there is no time lug. Users can manually adjust the endocardial border if the semi-automated border is insufficient. One investigator who was blinded to any vital data calculated stroke volume (SV), cardiac output, and CI from the left ventricular volume measurements.

A second observer determined the CI in ten randomly selected patients to determine interobserver variability to assess reproducibility. To determine intraobserver variability, the observer performed CI measurements twice with the same data set, with a 1-week interval.

Determining CI with ClearSight™

The ClearSight™ method is based on measuring finger arterial pressure with an inflatable cuff around the middle phalanx. The pulsating finger artery is maintained at a constant volume by applying a varying counter-pressure equivalent to the arterial pressure with a built-in photoelectric plethysmograph and an automatic algorithm. The resulting finger arterial pressure wave form is reconstructed into a brachial artery pressure waveform with a generalized algorithm [10]. The CI was calculated with a pulse contour method, using the measured systolic pressure–time integral, and the heart's afterload was determined using the Windkessel model [16]. Based on this algorithm, the CI is updated every 20 s.

Statistical methodology

All data are expressed as means ± standard deviation (SD) or number. Patients' hemodynamic data were compared using a paired *t*-test. All statistical analyses were performed with statistical software (EZR statistical software, Saitama Medical Center, Jichi Medical University, Saitama, Japan; available at http://www.jichi.ac.jp/saitama-sct/SaitamaHP.files/statmedEN.html) [17]. EZR is a modified version of the R commander (R Foundation for Statistical Computing, Vienna, Austria). A value of $p < 0.05$ was considered to indicate statistical significance.

The Bland–Altman method was used to compare CI_{CS} with CI_{3D}. The results of this analysis are presented as bias, percentage error, and 95% limits of agreement [18] The percentage error was calculated as follows:

$$\text{Percentage error} = (2\ \text{SD of the bias})/(\text{mean CI of the reference method}).$$

The test method (CI_{CS}) was evaluated as being interchangeable with the reference method (CI_{3D}) if it was < 30%. We also conducted a subanalysis by dividing the data sets into two groups according to the measured CI_{3D} as follows: (1) $CI_{3D} < 2.5$ L/min/m^2 (L group) and (2) $CI_{3D} \geq 2.5$ L/min/m^2 (H group). The cut off value of 2.5 L/min/m^2 was defined according to the previous researches which defined low cardiac index as < 2.5L/min/m^2 [19, 20]. The percentage error was calculated in each group. In addition, we examined the unadjusted relation between CI_{3D} and the ratio of the discrepancy in CI [i.e., $(CI_{CS} - CI_{3D})/CI_{3D}$] with a cubic spline function to identify any inflection point. We also examined the unadjusted relation between $SVRI_{3D}$ and the ratio of the discrepancy in the CI [i.e., $(CI_{CS} - CI_{3D})/CI_{3D}$] with a cubic spline function.

Four-quadrant plot analysis was performed to assess the concordance rate, which was defined as good when it was > 92% [21]. The concordance rate was defined as the percentage of data points lying in the upper right or lower left quadrant of the four-quadrant plot. The concordance rate was calculated at the following time points: after aortic clamping (between T2 and T3) and after aortic unclamping (between T5 and T6). In accordance with a previous study, we set an exclusion zone, which we defined as the area of percentage change in CI < 10% [22]. Then, polar plot analysis was performed to compare the trending abilities of the CI_{CS}. Polar plot analysis reveals agreement between two methods by the angle from the line of identity ($y = x$) and the magnitude of change by the length of the vector [21, 23]. Polar plot analysis requires that the plots used in the four-quadrant plot analysis be rotated 45° in the clockwise direction. The statistical variables calculated from the polar plot analysis are the mean angular bias (average angle from the axis), radial limits of agreement (radial sector containing 95% of the total number of data points), and angular concordance rate (percentage of points within a ± 30° radial zone). A previous study indicated that the agreement between the two methods is excellent if the following limits are met: (1) angular bias < ± 5°; (2) angular concordance rate > 95%; and (3) radial limit of agreement < ± 30° [23].

The interobserver and intraobserver variabilities were measured according to the following formula:

$$\left(SD_{diff} \times 100\%\right)/\text{total mean} \times \sqrt{2},$$

where SD_{diff} is the SD of the difference between measurements.

Results

Patients' characteristics are shown in Table 1. Twenty patients (1 woman, 19 men) were enrolled. Table 2 shows hemodynamic data at each time point. MAP, MAP_{CS}, and the $SVRI_{3D}$ increased significantly after aortic clamping (T2 versus T3; $p < 0.001$ for both MAP and MAP_{CS}; $p < 0.01$ for $SVRI_{3D}$). Although the CI_{CS} increased significantly after aortic clamping ($p < 0.05$), CI_{3D} did not change significantly. MAP, MAPcs, and $SVRI_{3D}$ decreased significantly after aortic unclamping (T5 versus T6, all $p < 0.001$). The differences in CI (both CI_{CS} and CI_{3D}) after aortic unclamping were not significant.

The Bland–Altman analyses comparing CI_{CS} and CI_{3D} for all measures are shown in Fig. 1a. The percentage error was 41.3%, indicating that CI_{CS} had a wide limit of agreement with CI_{3D}.

Table 1 Patient characteristics

	All patients ($n=20$)
Age range (years)	54–79
Sex (M/F)	19/1
Height (cm)	166.1 ± 6.0
Body weight (kg)	65.7 ± 9.5
Ejection fraction (%)	72.7 ± 9.1
Valve	
MR (mild/trivial/none)	1/13/6
AR (mild/trivial/none)	2/5/13

Data are presented as mean ± standard deviation or number

MR mitral regurgitation, *AR* aortic regurgitation

Next, we performed a subanalysis of the measured CI sets divided into two groups according to the measured CI_{3D} as follows: (1) $CI_{3D} < 2.5$ L/min/m^2 (71 sets; L group) and (2) $CI_{3D} \geq 2.5$ L/min/m^2 (89 sets; H group). Figure 1b shows that the percentage error was 45.3% in L group and 33.2% in H group. Based on the results that the percentage error in L group was higher than that of H group, ClearSight™ was likely not accurate in patients with low CI, especially in those with CI < 2.5 L/min/m^2. We compared the $SVRI_{3D}$ between the groups, revealing that the $SVRI_{3D}$ in the L group was significantly higher than that in H group (1821 ± 541 versus 2318 ± 700 dyne s/cm^5/m^2, respectively; $p < 0.001$). The higher $SVRI_{3D}$ in patients with CI < 2.5 L/min/m^2 possibly had an impact on the accuracy of ClearSight™.

Figure 2a shows that the cubic splines related to the CI_{3D} and CI discrepancy were negatively sloped, indicating that CI_{3D} had a significant effect in the CI discrepancy ($p < 0.001$). There was an inflection point at approximately 2.5–3.5 L/min/m^2, after which the CI discrepancy [($CI_{CS} - CI_{3D}$)/CI_{3D}] almost plateaued near zero. Figure 2b shows that the cubic splines related to the SVRI3D and CI discrepancy were positively sloped, indicating that SVRI3D had a significant effect in the CI discrepancy ($p < 0.001$).

Next, we used a four-quadrant plot analysis to examine the trending ability of CI_{CS} at the timing of aortic clamping and unclamping. The concordance rate was 81.3% after aortic clamping (Fig. 3a) and 78.6% after aortic unclamping (Fig. 3b). To investigate the effect of CI on trending ability, we included only points with CI ≥ 2.5 L/min/m^2 (eight points after aortic clamping and six points after aortic unclamping, respectively). Then, the concordance rate was 100% after aortic clamping and 100% after aortic unclamping (Supplementary Table 1).

Finally, polar plot analysis showed that the mean angular biases, the radial limits of agreement, and the concordance rate after aortic clamping were − 18.8°, 34.5°, and 58.3%, respectively (Fig. 4a). Polar plot analysis also showed that the mean angular biases, the radial limits of agreement and the concordance rate after aortic unclamping were − 17.5°, 38.4°, and 66.7%, respectively (Fig. 4b). Both angular concordance rates were below the acceptable limit (> 95%). To investigate the effect of CI on trending ability, we included only points with CI ≥ 2.5 L/min/m^2 (ten points after aortic clamping and five points after aortic unclamping, respectively). Then, the concordance rate was 75% after aortic clamping and 80% after aortic unclamping (Supplementary Table 2).

The intraobserver variability was 14.1% and interobserver variability was 13.1%.

Table 2 Time course of changes in hemodynamic data

	T1	T2	T3	T4	T5	T6	T7	T8
HR (bpm)	57 ± 10	64 ± 9**	61 ± 11	61 ± 11	61 ± 9	65 ± 11**	66 ± 10	74 ± 12**
MAP (mmHg)	72 ± 10	67 ± 6	79 ± 9***	74 ± 7*	68 ± 7**	57 ± 8***	64 ± 10***	74 ± 10**
MAP_{CS} (mmHg)	69 ± 9	65 ± 9	77 ± 11***	71 ± 7*	69 ± 8	58 ± 7***	65 ± 11**	74 ± 8**
CVP (mmHg)	8.2 ± 2.7	9.3 ± 2.5	10.4 ± 3.0**	8.8 ± 3.1**	8.4 ± 2.1	8.4 ± 2.6	10.0 ± 2.6**	7.9 ± 2.4**
CI_{3D} (L/min/m^2)	2.3 ± 0.5	2.6 ± 0.5*	2.5 ± 0.7	2.5 ± 0.5	2.4 ± 0.5	2.6 ± 0.8	2.9 ± 0.6**	3.3 ± 0.9**
CI_{CS} (L/min/m^2)	2.4 ± 0.5	2.7 ± 0.4**	2.9 ± 0.5*	2.9 ± 0.5	2.9 ± 0.5	2.9 ± 0.6	3.2 ± 0.6***	3.5 ± 0.8*
$SVRI_{3D}$ (dyne s/cm^5/m^2)	2308 ± 652	1814 ± 420**	2393 ± 881**	2698 ± 877	2065 ± 516	1638 ± 559***	1558 ± 377	1677 ± 433
Percentage error (%)	38.3	33.1	38.4	30.9	42.5	44.0	42.8	48.1

HR heart rate, *MAP* mean arterial pressure, MAP_{CS} mean arterial pressure measured with ClearSight™, *CVP* central venous pressure, CI_{3D} cardiac index measured with three-dimensional transesophageal echocardiography, CI_{CS} cardiac index measured with ClearSight, $SVRI_{3D}$ systemic vascular resistance index using CI_{3D}

T1 after anesthesia induction, *T2* immediately before aortic cross-clamping, *T3* immediately after aortic cross-clamping, *T4* 5 min after aortic cross-clamping, *T5* immediately before the first unclamping of the iliac artery, *T6* immediately after the first unclamping of the iliac artery, *T7* 5 min after the first unclamping of the iliac artery, *T8* at the end of surgery

Data are shown as mean ± standard deviation; *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$ compared with the previous measurement

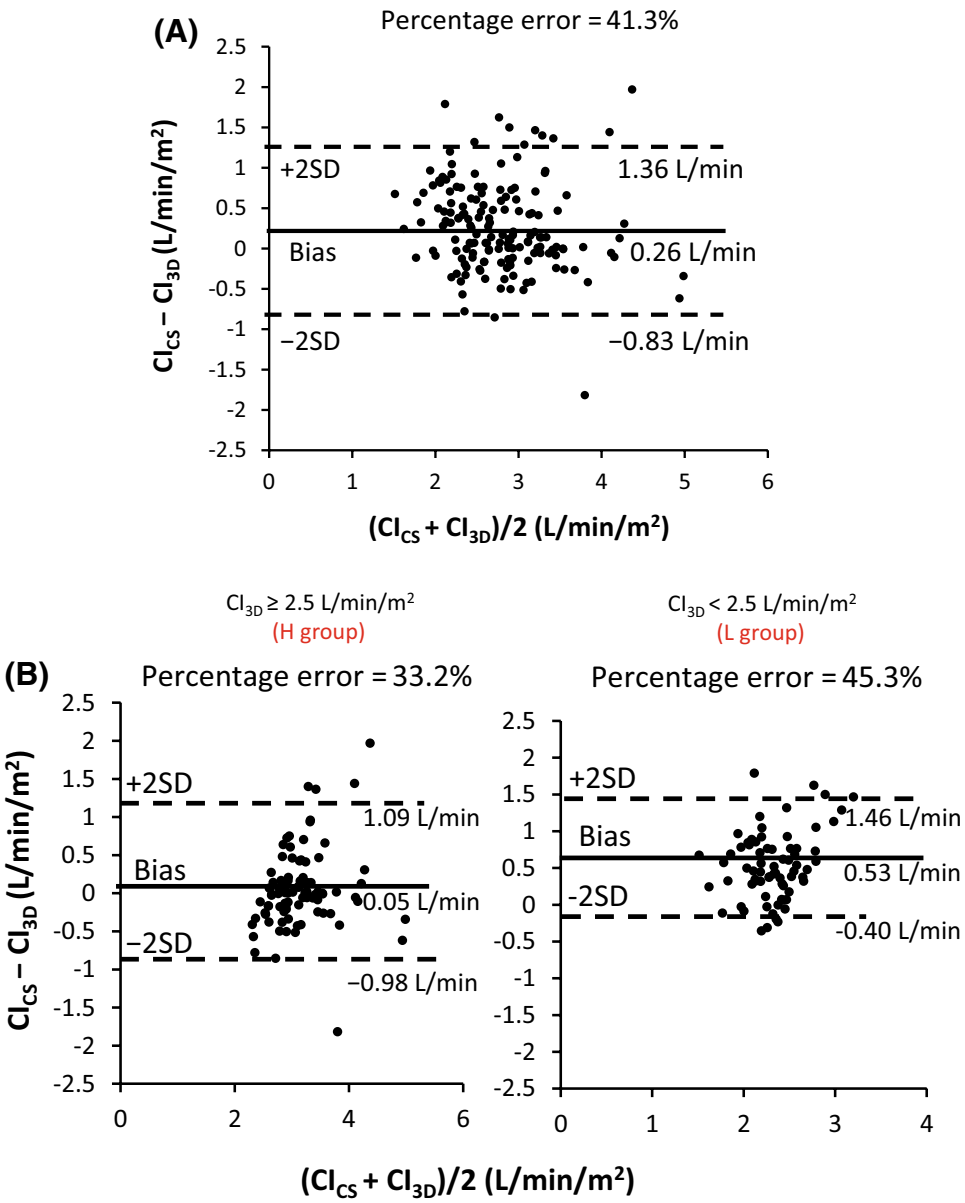

Fig. 1 **a** Bland–Altman analysis to examine the reliability of CI_{CS} versus CI_{3D}. **b** Bland–Altman analysis to examine the reliability of CI_{CS} versus CI_{3D} in patients with $CI_{3D} \geq 2.5$ L/min/m^2 (left) and $CI_{3D} < 2.5$ L/min/m^2 (right). Bland–Altman analysis shows the mean bias (right line) and 95% limits of agreement (dashed lines). *CI* cardiac index, CI_{3D} cardiac index determined with 3D transesophageal echocardiography, CI_{CS} ClearSight™-derived cardiac index

Discussion

We found that CI_{CS} is not interchangeable with CI_{3D} in patients undergoing AAA surgery. The cubic spline model showed that CI discrepancy increased as the CI_{3D} decreased. We also revealed that the trending ability of the ClearSight™ system was not clinically acceptable, after either aortic clamping or unclamping.

Previous studies assessed the accuracy of ClearSight™ in tracking CI changes over time. In general, ClearSight™ has performed well, with reported levels of concordance between 84 and 100% [11, 24–26]. These studies used a prespecified hemodynamic intervention, such as a fluid challenge [24, 26, 27] or administration of phenylephrine [25], to assess dynamic tracking ability. Our study revealed that the concordance rate was not acceptable both after aortic clamping and after the first unclamping of the iliac artery. In this view, our study contradicts previous studies. One of the explanations is the rapid increase in the SVRI during cross-clamping. When a surgeon clamps the aorta, it leads to rapid surges in the SVRI that cannot be compared with that caused by phenylephrine administration. It follows that the algorithm of ClearSight™ may be inaccurate under the condition of dramatic SVRI changes caused by aortic clamping. Also, our results revealed that the ClearSight™ system was inaccurate especially in patients with low cardiac output. Because our data sets included 71 datapoints (44.4%) with $CI_{3D} < 2.5$ L/min/m^2, it may affect the trending ability of the ClearSight™ system. These findings provide new insights of the limitations of the ClearSight™ system to

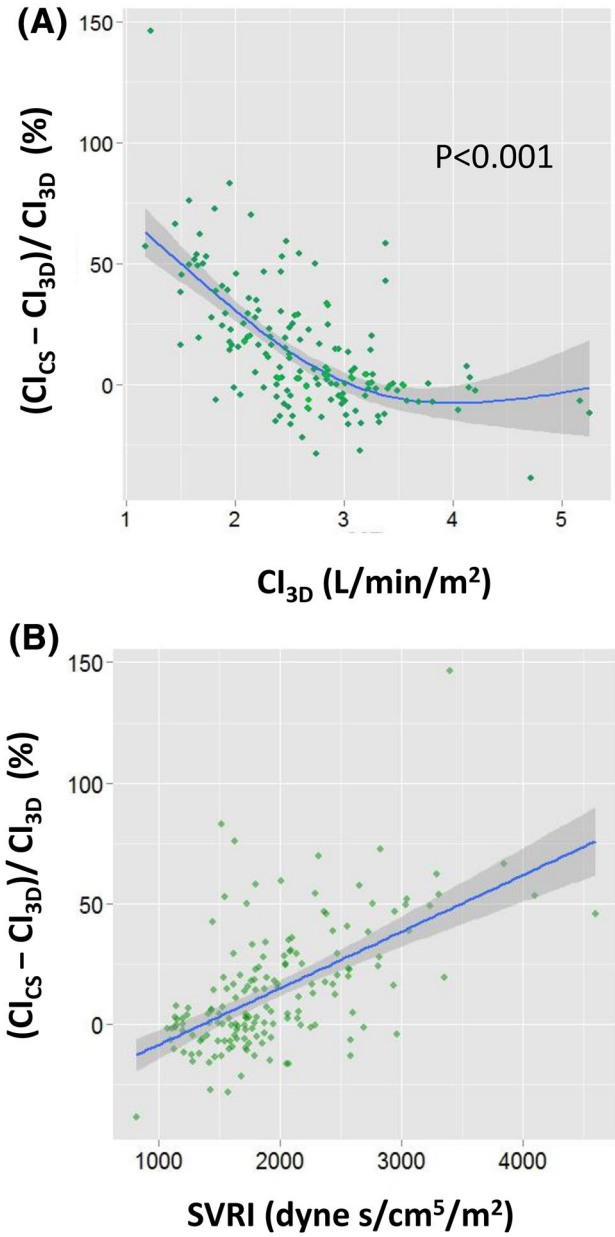

Fig. 2 **a** Cubic spline function curves of the relation between the CI_{3D} and CI discrepancy [$(CI_{CS} - CI_{3D})/CI_{3D}$]. **b** Cubic spline function curves of the relation between SVRI3D and CI discrepancy [$(CI_{CS} - CI_{3D})/CI_{3D}$]. *CI* cardiac index, CI_{3D} cardiac index determined with 3D transesophageal echocardiography, CI_{CS} ClearSight™-derived cardiac index, *SVRI3D* systemic vascular resistance index. Shaded areas represent 95% confidence intervals

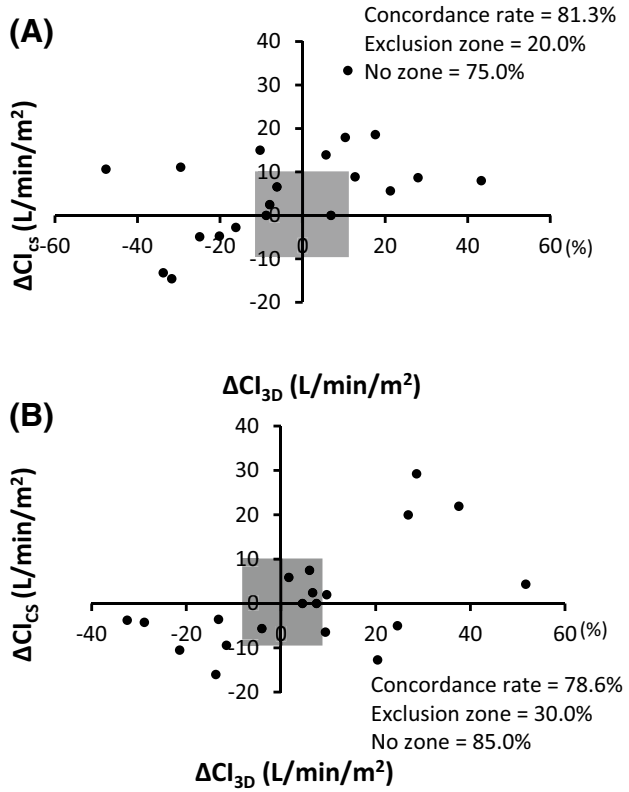

Fig. 3 Four-quadrant plot analysis used to examine the trending ability for ΔCI_{CS} compared with ΔCI_{3D}. Shaded gray zone is an exclusion zone that was set as the percentage change in cardiac output < 10%. **a** After aortic clamping (between T2 and T3). **b** After first unclamping of the iliac artery (between T5 and T6). ΔCI_{CS} cardiac output change measured with ClearSight™, ΔCI_{3D} cardiac output change measured with 3D transesophageal echocardiography

select the appropriate patients. Although our additional analysis revealed that there is a significant relationship between MAP and MAPcs ($r^2 = 0.69$, $P < 0.001$; data not shown), the measurement of CI is not accurate in patients with AAA surgery. Based on our results, it may not be appropriate to apply ClearSight™ to monitor the cardiac output in patients who undergo AAA surgery.

There are some limitations in our study. First, although we excluded patients who had more than mild MR or AR, we enrolled some patients with criteria of less than or equal to a diagnosis of mild MR or AR. It follows that there is a possibility of overestimation of SV or CI_{3D} in MR patients because we measured SV as the difference between end-diastolic volume and end-systolic volume. Similarly, we may have underestimated the SV and/or CI_{3D} in the AR patients. However, a previous study revealed that the regurgitant fraction in mild MR was < 30% [28]. Because our study included only one patient with mild MR, the regurgitant fraction was likely far less than 30% in most patients, which would affect the results only minimally. Similarly, we included two patients with mild AR, which may have affected our results. However, these patients had mild or trivial MR, which could offset the underestimation of SV or CI_{3D}. Aside from these exceptions, the rest of the patients had less than trivial AR, which likely caused minimal effects. Second, the overall sample size was relatively small. Therefore, very small subgroups were available when it came to validating the effect

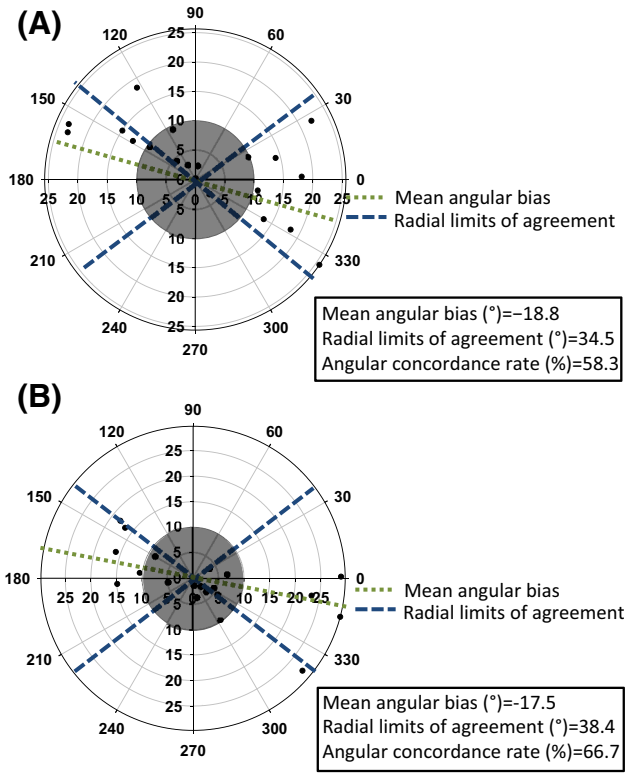

Fig. 4 Polar plots used to examine the trending ability for ΔCI_{CS} compared with ΔCI_{3D}. Shaded gray area is an exclusion zone of 10%. **a** After aortic clamping (between T2 and T3). **b** After first unclamping of the iliac artery (between T5 and T6). ΔCI_{CS} cardiac output change measured with ClearSight™, ΔCI_{3D} cardiac output change measured with 3D transesophageal echocardiography

of CI on trending ability. Sample size calculation may be possible if we use the desired maximal width for the 95% CIs around the mean error. However, we measured CI in eight points and the hemodynamic instability was expected at some points. In addition, to the best of our knowledge, this study is the first study to investigate the accuracy of ClearSight™ during AAA surgery. Therefore, it was impossible to set the mean error beforehand. Third, although we could investigate the association between high SVRI and inaccuracy of ClearSight™, we could not profoundly address the impact of low SVRI to accuracy as the data with low SVRI is limited. Fourth, in case of aortic clamping, we usually increase the concentration of inhaled sevoflurane in order to adjust the blood pressure. Also, in two cases, anesthesiologist who was in charge administered 0.1 mg of phenylephrine to adjust blood pressure. Catecholamine use was left at the discretion of the attending anesthesiologist. Low-dose dopamine was used in eight patients. These actions might have affected our results. Fifth, in some points, the discrepancy between CIcs and CI_{3D} was very high [$(CI_{CS} - CI_{3D})/CI_{3D} > 50\%$]. Although we could not elucidate the reason, this might have affected the percentage error in each time point. Lastly, there may be differences in response time between CIcs and CI_{3D}. CI_{3D} is the real-time monitor of CI. Meanwhile, ClearSight™ has some time to update the calculated CI. However, we think this discrepancy is minimal because it will take only 20 s to update the CI in ClearSight™.

In conclusion, we revealed that the accuracy of the ClearSight™ system is unacceptable in patients undergoing AAA surgery. The rapid surge of SVRI caused by aortic clamping and low CI may contribute to this inaccuracy. Also, it was not clinically acceptable for the ClearSight™ system to track CI changes after aortic clamping and unclamping.

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Compliance with ethical standards

Conflict of interest This research was supported in part by JSPS KAKENHI Grant number JP17K11100.

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